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SEAGER, TUFTE & WICKHEM, LLC
1221 Nicollet Avenue
Suite 800
Minneapolis, MN 55403

EXAMINER	
SWEET, THOMAS	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GIL M. VARDI, CHARLES J. DAVIDSON, and ERIC WILLIAMS

Appeal 2010-001251
Application 10/762,562
Technology Center 3700

Before JENNIFER D. BAHR, STEFAN STAICOVICI and PHILLIP J. KAUFFMAN, *Administrative Patent Judges*.

STAICOVICI, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Gil Vardi et al. (Appellants) appeal under 35 U.S.C. § 134 from the Examiner's decision to reject under 35 U.S.C. § 103(a) claims 1-7, 9 and 24 as unpatentable over Wilson (US 6,165,195, issued Dec. 26, 2000) and Fischell (US 5,749,825, issued May 12, 1998). Claims 8 and 10-23 have been canceled. We have jurisdiction over this appeal under 35 U.S.C. § 6.

THE INVENTION

Appellants' invention relates to methods of positioning a main stent 25 at a vessel bifurcation B such that a side opening 27 in main stent 25 is positioned at the ostium of a branch vessel Br. Spec. 7, ll. 6-8 and figs. 5 and 6A.

Claim 7 is representative of the claimed invention and reads as follows:

> 7. A method of positioning a main stent at a vessel bifurcation between a main vessel and a branch vessel such that a side opening in the main stent is positioned at an ostium of the branch vessel, the method comprising:
>
> positioning a main guidewire in the main vessel such that a distal end of the main guidewire extends past the bifurcation;
>
> advancing a stent delivery system over the main guidewire to a position proximate the bifurcation, the stent delivery system comprising a catheter with a flexible side sheath attached thereto, wherein the catheter is received over the main guidewire, and wherein the main stent is positioned over the catheter with the flexible side sheath positioned to pass through the interior of the main stent and out the side opening in the main stent, the flexible side sheath having a distal end portion extending distal of the side opening of the stent;

> subsequently, advancing a branch guidewire through the flexible side sheath and into the branch vessel; and
>
> subsequently, advancing the catheter over the main guidewire while advancing the flexible side sheath over the branch guidewire, wherein the distal end portion of the flexible side sheath advances into the branch vessel such that the side opening in the main stent is positioned at the ostium of the branch vessel.

SUMMARY OF DECISION

We AFFIRM-IN-PART.

OPINION

Claims 1 and 7

Appellants present essentially identical arguments with respect to the rejections of independent claims 1 and 7 under 35 U.S.C. § 103(a) as unpatentable over Wilson and Fischell. App. Br. 11-12 and 14-16. As such, the following analysis applies equally to both independent claims 1 and 7.

Appellants first argue that the combination of Wilson and Fischell fails to teach or suggest "the flexible sheath having a distal end portion extending distal of the side opening of the stent," as required by independent claims 1 and 7. App. Br. 11 and 15. *See also* App. Br., Claims Appendix. Specifically, Appellants argue that Fischell discloses a sheath having a proximal end that extends only a short distance proximal of the stent. App. Br. 12 and 15. As such, according to Appellants, the stent delivery system of Fischell would need to be advanced over the branch guidewire prior to, as opposed to subsequent to, the stent delivery system being advanced through the vessel. *Id.*

We are not persuaded by Appellants arguments, because Appellants appear to attack the teachings of Wilson and Fischell individually, rather than the combination of Wilson and Fischell. Nonobviousness cannot be established by attacking the references individually when the rejection is predicated upon a combination of prior art disclosures. *See In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Further, obviousness does not require that all of the features of the secondary reference be bodily incorporated into the primary reference. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981).

In this case, the Examiner found that Wilson discloses all the limitations of claims 1 and 7 with the exception of extending distal end portion of flexible side sheath 55B distal of side opening 25 of stent 20. Ans. 4. The Examiner further found that Fischell discloses extending distal end portion of flexible side sheath 24 distal of side opening 27 of stent 20. *Id. See also* Fischell, fig. 1. As such, Appellants' claimed stent positioning method is nothing more extending the distal end portion of flexible side sheath 55B of Wilson distal of side opening 25 of stent 20 of Wilson, as taught by Fischell. Extending the distal end portion of flexible side sheath 55B of Wilson distal of side opening 25 of stent 20, as taught by Fischell, would not have been uniquely challenging to a person of ordinary skill in the art, because it is "the mere application of a known technique to a piece of prior art ready for the improvement." *KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). The modification appears to be the product not of innovation but of ordinary skill and common sense. An improvement that is nothing more than the predictable use of prior art elements according to their established functions is likely to be obvious. *Id.* Consequently, we agree

with the Examiner that that it would have been obvious for a person of ordinary skill in the art to modify the distal end portion of the flexible side sheath of Wilson to extend distal of the side opening of the stent, as taught by Fischell, in order to help assure proper longitudinal placement of main stent 20 relative to the bifurcation of main vessel 6 and side vessel 5. Ans. 4-5.

As such, in contrast to Appellants' position, we find that the flexible side sheath 55B of Wilson, as modified by Fischell, constitutes a "flexible side sheath having a distal end portion extending distal of the side opening of the stent," as required by independent claims 1 and 7.

Second, Appellants argue that neither Wilson nor Fischell, either alone or in combination, appears to teach or suggest the method step of "viewing relative movement of a marker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter," as required by claim 1. App. Br. 9 and 16. *See also* App. Br., Claims Appendix. Appellants argue that Wilson discloses using a radiopaque marker on a single lumen of a respective catheter to determine the proper orientation and alignment of the catheter with the side branch vessel. App. Br. 10 and 16-17. As such, according to Appellants, in such a configuration, "there would appear to be no relative movement between the marker(s)." App. Br. 10. Appellants further argue that Wilson fails to "disclose multiple radiopaque markers or multiple catheter components having radiopaque markers on a catheter." Reply Br. 2.

We find Appellants' arguments unpersuasive for the following reasons. First, as noted above, Appellants' arguments appear to attack the teachings of Wilson and Fischell individually, rather than the combination of

Wilson and Fischell. Furthermore, we find that Appellants' arguments are not commensurate in scope with the Examiner's proposed combination of Wilson and Fischell.

The Examiner is proposing to further add a radiopaque marker to the distal end of the flexible side sheath of Wilson as modified by Fischell. *See* Ans. 4-5. Specifically, the Examiner takes the position that main stent 20 of Wilson constitutes the claimed "at least one marker positioned on the catheter [50 of Wilson]." Ans. 4. *See also* Wilson, col. 13, ll. 10-14 and fig. 13A. The Examiner further takes the position that although Wilson does not specifically disclose a radiopaque marker positioned on the distal end portion of flexible side sheath 55B, because Wilson discloses placing markers on catheter components (e.g., guide wire lumen 55A (flexible side sheath)) for the purpose of assisting in proper alignment, this would lead a person of ordinary skill in the art to add a radiopaque marker to the distal end of the flexible side sheath of Wilson, as modified by Fischell, to further assist in proper alignment. Ans. 4-6. *See also* Wilson, col. 17, l. 64 through col. 18, l. 14.

At the outset, although Wilson does not explicitly disclose stent 20 as a marker, nonetheless, we agree with the Examiner that main stent 20 can be reasonably construed as a marker on catheter 50 of Wilson. An artisan must be presumed to know something about the art apart from what the references disclose. *See In re Jacoby*, 309 F.2d 513, 516 (CCPA 1962). We further agree with the Examiner's position that a person of ordinary skill in the art would have readily recognized that because guide wire lumen 55A (flexible side sheath) of Wilson can have a radiopaque marker and since a stent can be a radiopaque marker, adding a marker to the distal end 55B of guide wire

lumen 55A (flexible side sheath) of Wilson, as modified by Fischell, would have been obvious to a person of ordinary skill in the art "to further assist in proper alignment." *See* Ans. 5. Such a modification is nothing more than the predictable use of prior art elements according to their established functions. *See KSR*, 550 U.S. at 417. Hence, we agree with the Examiner that in the *combination* of Wilson and Fischell, as described above, the movement of the radiopaque marker positioned on the distal end portion 55B of the flexible side sheath 55A of Wilson, as modified by Fischell, is viewed relative to the at least one marker, i.e., stent 20, positioned on catheter 50, as called for by independent claim 1. *See* Ans. 5-6.

In conclusion, for the foregoing reasons, we shall sustain the rejection of independent claims 1 and 7 under 35 U.S.C. § 103(a) as unpatentable over Wilson and Fischell.

Claims 4-7, 9, and 24

Although Appellants argue the rejection of claim 9 over the combined teachings of Wilson and Fischell under a separate heading, Appellants do not make any other substantive arguments. App. Br. 16-17. Accordingly, the rejection of claim 9 under 35 U.S.C. § 103(a) as unpatentable over Wilson and Fischell is likewise sustained.

Lastly, Appellants do not argue dependent claims 4-6 and 24 separate from independent claim 1. App. Br. 8. Accordingly, the rejection of dependent claims 4-6 and 24 over the combined teachings of Wilson and Fischell is also sustained.

Claim 2

Appellants argue that Wilson fails to disclose using radiopaque marker(s) on both the main guidewire lumen and the secondary guidewire lumen of the catheter. App. Br. 13. As such, according to Appellants, Wilson fails to disclose the method step of "viewing an increasing separation distance between the marker positioned on the flexible side sheath with respect to the at least one marker positioned on the catheter," as required by dependent claim 2. *Id.*

We are not persuaded by Appellants' arguments, because, again, Appellants appear to attack the teachings of Wilson and Fischell individually, rather than the combination of Wilson and Fischell. As discussed above, since the *combination* of Wilson and Fischell includes a radiopaque marker positioned on the distal end portion 55B of the flexible side sheath 55A of Wilson, as modified by Fischell, and another marker, *i.e.* stent 20, on catheter 50, we find that the combined teachings of Wilson and Fischell reasonably discloses the method step of "viewing an increasing separation distance between the marker positioned on the flexible sheath with respect to the at least one marker positioned on the catheter," as called for by claim 2.

Accordingly, for the foregoing reasons, the rejection of dependent claim 2 under 35 U.S.C. § 103(a) as unpatentable over Wilson and Fischell is sustained.

Claim 3

Dependent claim 3 discloses the method step of "viewing the at least one marker positioned on the catheter comprises viewing markers positioned

adjacent the distal and proximal ends of the main stent." App. Br., Claims Appendix. In this case, although we appreciate the Examiner's position that main stent 20 constitutes the claimed at least one marker on catheter 50 of Wilson, we could not find any portion of Wilson, and the Examiner has not pointed to any portion of Wilson, that discloses additional markers positioned adjacent the distal and proximal ends of main stent 20, as required by dependent claim 3. The addition of Fischell does not remedy the deficiencies of Wilson as discussed above.

Hence, for the foregoing reasons, the rejection of dependent claim 3 under 35 U.S.C. § 103(a) as unpatentable over Wilson and Fischell cannot be sustained.

DECISION

The decision of the Examiner is affirmed as to claims 1, 2, 4-7, 9 and 24 and reversed as to claim 3.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART

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